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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,776	05/05/2005	Rainer Albert	TX/4-32662A	5246

1095 7590 07/18/2007

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,776	ALBERT ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-24* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☒ Claim(s) *9-11* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated May 3, 2007 have been entered and considered carefully.

All the pending claims 1-8 have been canceled. New claims 9-24 are pending.

2. The newly added claims 9-24 are subject to restriction:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 9-11, drawn to compounds, compositions thereof and process of making, classified in class 546, subclass 187.

II. Claims 12-15, drawn to multiple active ingredient composition, classified in class 514, subclass various, depending on species election.

III. Claims 16-24, drawn to method of treating diseases, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed compound for a single disclosed disease is also required.

Multiple active ingredient composition are independent and patentably distinct from single active ingredient composition because the dosage, carrier and chemical properties of such composition different from each active ingredient and interaction must be examined separately.

In so far as the instantly amended compounds are concerned, nowhere in the specification a "combination" composition with any specific co-agent was disclosed, i.e. lacking antecedent basis. Nor was a combination composition with any specific co-agent was made. While multiple drugs can be given to subject simultaneously, a single "composition" containing multiple active ingredient must be provided as to what the specific ingredients are and how it is made. Please note that the specification provided no specific description as to what the co-agent can be and how a single formulation for two active ingredient can be made. Chemical compounds have vast difference in solubility, stability, etc. without knowing "which" co-agent is being formulated, therefore, separate search and examination must be conducted independently.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating transplant rejection can be practice with the conventional immunosuppressant such as FK 506 (see Youhua et al.).

Based on the original election, group I, claims 9-11 are continuously prosecuted for merit examination. Claims 12-24 are withdrawn from consideration per 37 CFR 1.142(b).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior to* final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be **allowable**, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai; In re Brouwer and 35 U.S.C.§ 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-trough" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease*

named with efficacy support from the specification for treating the particular disease. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

3. The newly added claims 16-24 cannot be rejoined because the claims are drawn to such incredible scope for which description and enablement of the compounds for such method cannot be supported by the specification.

It is noted that the claims are drawn to both disease that resulted from CCR5 agonist (see CA 134:250801) and antagonist (Thoma et al.), while the specification explicitly described that the instantly claimed compounds are CCR5 antagonists (p. 17). Further, no nexus was found between the claimed compound and the breadth of such treatment with unrelated diversity (a Wands analysis with respect to the subject matter in the previous office action is hereby incorporated by reference). Limited support is found in the art that the claimed compounds is a promising candicate for kidney allograft rejection (Thoma et al.) but no claim is found to this scope.

4. Applicants have obviated the obviousness type double patenting by filing an acceptable terminal disclaimer, therefore, the rejection of claims 1-5 which is now applicable to newly added claims 9-11 is dropped.

Applicants have obviated the 103(a) rejection of claims 1-5 which is now applicable to newly added claims 9-11 by disqualify the '559 reference being a 103(c) reference since assignment record indicated common ownership at the time this application was filed (PCT filing date for the instant application is Oct. 7, 2003 applicants Norvatis). Therefore, the 103(a) rejection is dropped.

The rejection of claims 1-5 which is now applicable to newly added claims 9-11 over Baroudy et al. '559 in view of Asberom et al. '425 is dropped in view of applicants' argument

that Asberom et al. '425 is not analogous art since Asberom's compounds are muscarinic receptor inhibitors.

5. This application is in condition for allowance except for the following formal matters:

Cancellation of the non-elected claims 12-24.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
July 8, 2007

Celia Chang
Primary Examiner
Art Unit 1625